



PATENT  
Attorney Docket No.: 021385-014010US

#6

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Meikle et al.

Application No.: 09/936,957

Filed: September 17, 2001

For: DIAGNOSIS OF LYSOMAL  
STORAGE DISORDERS USING  
SAPOSINS AND OTHER MARKERS

Examiner: Unassigned

Art Unit: 1641

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT UNDER 37  
CFR §1.97 and §1.98

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Assistant Commissioner for Patents  
Washington, D.C. 20231

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The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the references are enclosed. Also enclosed is a copy of the International Search Report for the Corresponding PCT application. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

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Respectfully submitted,



Joe Liebeschuetz  
Reg. No. 37,505

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Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	2
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**Complete if Known**

<b>Application Number</b>	09/936,957
<b>Filing Date</b>	September 17, 2001
<b>First Named Inventor</b>	Meikle
<b>Art Unit</b>	1641
<b>Examiner Name</b>	Unassigned
<b>Attorney Docket Number</b>	021385-014010US

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

**Examiner  
Signature**

Date  
Considered

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	09/936,957	
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			Examiner Name	Unassigned	
Sheet	2	of	2	Attorney Docket Number	021385-014010US

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AC	ALEXANDER et al., "5 Related Lebanese Individuals with high Plasma Lysosomal Hydrolases A New Defect in Mannose-6-Phosphate Receptor Recognition," <u>Am. J. Human Genetics</u> , 36(5):1001-1014 (1984).	
	AD	BROOKS et al., "Immunoquantification of the Low Abundance Lysosomal Enzyme N-acetylgalactosamine 4-sulphatase," <u>J. Inherited Metabolic Disease</u> , 13(1):108-120 (1990).	
	AE	GATTI et al., "Comparative Study of 15 Lysosomal Enzymes in Chorionic Villi and Cultured Amniotic Fluid Cells. Early Prenatal Diagnosis in Seven Pregnancies at Risk for Lysosomal Storage Diseases," <u>Prenatal Diagnosis</u> , 5(5):329-336 (1985).	
	AF	GRIFFITHS et al., "Plasma Acid Hydrolases in Normal Adults and Children, and in Patients with Some Lysosomal Storage Diseases," <u>Clinical Chimica Acta: Int. J. of Clinical Chemistry</u> , 90(2):129-141 (1978).	
	AG	HUA et al., "Evaluation of the Lysosome-Associated Membrane Protein LAMP-2 as a Marker for Lysosomal Storage Disorders," <u>Clinical Chemistry</u> , 44(10):2094-2102 (1998).	
	AH	KLEIMAN et al., "Sandhoff Disease in Argentina: High Frequency of a Splice Site Mutation in the HEXB Gene and Correlation Between Enzyme and DNA-Based Tests for Heterozygote Detection," <u>Human Genetics</u> , 94:279-282 (1994).	
	AI	LOVELL et al., "Biochemical and Histochemical Analysis of lysosomal Enzyme Activities in Caprine Beta-Mannosidosis," <u>Molecular and Chemical Neuropathology</u> , 21(1):61-74 (1994).	
	AJ	McCABE et al., "Preferential Inhibition of Lysosomal Beta Mannosidase by Sucrose," <u>Enzyme</u> , 43(3):137-145 (1990).	
	AK	O'BRIAN et al., "Saposin proteins: structure, function, and role in human lysosomal disorders," <u>FASEB J.</u> , 5(3):301-308 (1991).	
	AL	PRENCE et al., "Diagnosis of Alpha Mannosidosis by Measuring Alpha Mannosidase in Plasma," <u>Clinical Chemistry</u> , 38(4):501-503 (1992).	
	AM	TAGER, J.M., "Biosynthesis and deficiency of lysosomal enzymes," <u>TIBS</u> , 10(8):324-326 (1985)	
	AN	WHITLEY et al., "Long-term Outcome of Hurler Syndrome Following Bone Marrow Transplantation," <u>Am. J. Medical Genetics</u> , 46(2):209-218 (1993).	
	AO	YAMAGUCHI et al., "Improvement of Tear Lysosomal Enzyme Levels After Treatment with Bone Marrow Transplantation in a Patient with I-Cell Disease," <u>Ophthalmic Research</u> , 21(3):226-229 (1989).	
	AP	YUFENG et al., "Elevated Plasma Chitotriosidase Activity In Various Lysosomal Storage Disorders," <u>J. Inherited Metabolic Disease</u> , 18(6):717-722 (1995).	

Examiner Signature		Date Considered	
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# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/936,957
Filing Date	09/17/2001
First Named Inventor	Meikle
Group Art Unit	1641
Examiner Name	Unassigned
Attorney Docket Number	021385-014010US

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<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Response <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition Routing Slip (PTO/SB/69) and Accompanying Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s)	<input type="checkbox"/> After Allowance Communication Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): 1) Sixteen (16) cited references 2) Return receipt postcard 3) INTERNATIONAL SEARCH REPORT
Remarks		The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430. Total number of pages <u>does not</u> include cited references.

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm and Individual name	Townsend and Townsend and Crew LLP Joe Liebeschuetz	Reg No. 37,505
Signature		
Date	July 9, 2003	

## CERTIFICATE OF MAILING

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July 26, 2003

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